## IN THE SPECIFICATION

Please delete the paragraphs below which are proceeded with the direction "Delete the Paragraph." Paragraphs to delete from the specification are presented with only the first few words from the beginning of the paragraph, and the last few words of the paragraph. Please replace the paragraphs below which are proceeded with the direction "Replace the Paragraph." Paragraphs to replace are presented in full and with amendment markings.

**Delete the Paragraph at Page 14, lines 1-4.**

The paragraph to delete begins and ends as follows: "This method suffers from a serious limitation in that use of dichloromethane ... categorized by International Conference on Harmonization (ICH)."

**Delete the Paragraph at Page 14, lines 15-19.**

The paragraph to delete begins and ends as follows: "This method also suffers from a serious limitation in that use of chloroform ... categorized by International Conference on Harmonization (ICH).

**Delete the Paragraph at Page 14, lines 20-28.**

The paragraph to delete begins and ends as follows: "All the three abovementioned applications ... conditions of temperature, light, humidity or oxygen."

**Delete the Paragraph at Page 14, line 30 to Page 15, line 4.**

The paragraph to delete begins and ends as follows: "Against this backdrop ... embodied in WO 01/87835, WO 01/87836 and WO 01/83439."

**Delete the Paragraph at Page 15, lines 6-10.**

The paragraph to delete begins and ends as follows: "Further, the method disclosed in ... on the crystalline nature of the product thus obtained."

**Delete the Paragraph at Page 15, lines 12-29.**

The paragraph to delete begins and ends as follows: "However, as mentioned herein earlier, perindopril erbumine ... albeit not characterized and known to the public in large."

**Delete the Paragraph at Page 16, lines 16-24.**

The paragraph to delete begins and ends as follows: "iv) The crystal nature of perindopril erbumine ... product i. e. December 30, 1993 by the US FDA,"

**Delete the Paragraph at Page 16, lines 26-30.**

The paragraph to delete begins and ends as follows: "v) If the crystalline nature of perindopril erbumine ... not characterized and known to the public in large, and"

**Replace the Paragraph at Page 17, lines 1-4 with:**

~~vi)~~ iv) The known methods for crystallization of perindopril erbumine use solvents such as acetonitrile, chloroform, dichloromethane and 1,4-dioxane, all belonging to Class II as categorized by International Conference on Harmonization (ICH), thereby limiting their use on industrial scale for manufacture of the finished drug.

**Delete the Paragraph at Page 18, lines 22-26.**

The paragraph to delete begins and ends as follows: "e) Preparation of the α crystalline form ... pattern of the product thus obtained,"

**Delete the Paragraph at Page 18, lines 28-32.**

The paragraph to delete begins and ends as follows: "f) Preparation of the β crystalline form ... pattern of the product thus obtained, and"

**Delete the Paragraph at Page 19, lines 1-5.**

The paragraph to delete begins and ends as follows: "g) Preparation of the γ crystalline form ... pattern of the product thus obtained."

**Replace the Paragraph at Page 19, lines 8-30 with:**

The X-ray (powder) diffraction patterns of perindopril erbumine prepared and crystallized by the ~~six~~ four different methods mentioned hereinabove revealed that the powder pattern of :

i) those prepared as per methods (e), (f) and (g) conformed with/were identical to that of the α, β, and γ crystalline forms respectively disclosed in. WO 01/87835, WO 01/87836 and WO 01/83439,

ii) that prepared as per method (a) i.e. crystallization from ethyl acetate as per the method described in US. 4 914 214 was different from any of the α, β, and γ crystalline forms reported in. WO 01/87835, WO 01/87836 and WO 01/83439.

iii) that prepared as per method (b) i.e. crystallization from 1,4-dioxane as per the method described in US. 4 914 214 was also different from any of the α, β, and γ crystalline forms reported in. WO 01/87835, WO 01/87836 and WO 01/83439, and also different from the crystalline form obtained through method (a), but identical with that obtained through method (c), and

iv) that prepared as per method (c) i.e. crystallization from acetonitrile as per the method described in US. 4 914 214 was different from any of the α, β, and γ crystalline forms reported in. WO 01/87835, WO 01/87836 and WO 01/83439, and also different from the crystalline form obtained through method (a), but identical with that obtained through method (b).

**Replace the Paragraph at Page 20, lines 16-29 with:**

Various solvents, a list of which is given hereinbelow were tried for crystallization of perindopril erbumine, manufactured by any of the prior art methods or through methods invented by the inventors. These solvents are :

a) Ethers, both cyclic and acyclic, such as tetrahydrofuran, diethyl ether, diisopropyl ether etc.;
b) Ketonic solvents, both cyclic and acyclic, such as acetone, methyl ethyl ketone, methyl isobutyl ketone, 2-pentanone, cyclopentanone, cyclopentanone etc.;
c) Hydrocarbons, both aliphatic and aromatic, such as n-hexane, n-heptane, toluene, chlorobenzene etc;
d) Nitroalkanes, such as nitromethane, nitroethane, nitropropane etc.

~~However, all the solvents were found to give either the α- or β crystalline forms exclusively.~~

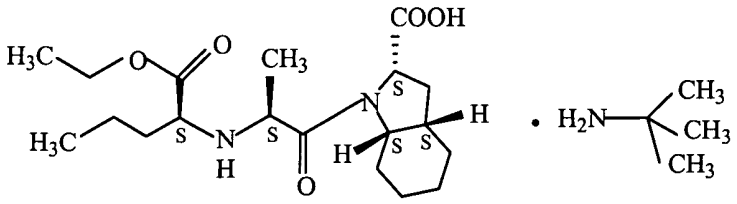
**Replace the Paragraph at Page 20, line 31 to Page 21, line 4 with:**

~~Against this backdrop, the~~ The applicants have found that solvents selected from N,N-dimethylformamide, ~~or~~ dimethyl acetals of lower aliphatic aldehydes, dimethyl

ketals of lower aliphatic ~~and~~ ketones and 1, 2- dialkoxyethane give exclusively the crystalline form of perindopril erbumine having identical and/or superimposable IR spectrum, DSC thermogram and X-ray (powder) diffraction pattern to that obtained on crystallization of perindopril erbumine from ethyl acetate as per the method described in Example Stage 3D, column 9 of US. 4 914 214.

**Replace the Paragraph at Page 21, line 20 to Page 23, line 7 with:**

Thus, in accordance with an aspect of the present invention there is provided a selective method for production of crystalline perindopril erbumine of formula (II), possessing the X-ray (powder) diffraction pattern, which moreover, is easily amenable for formulation into a dosage form and possesses sufficient stability on storage,



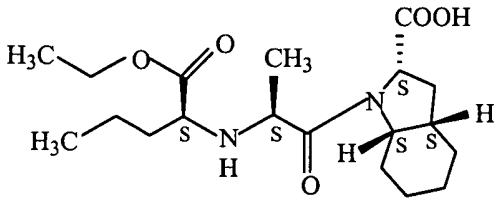
(II)

| ***d-spacing*** ***(Å)*** | ***Angle*** ***(⁰2θ)*** | ***Relative Intensity*** ***(%)*** |
|---|---|---|
| 10.239 | 8.628 | 1.16 |
| 8.886 | 9.945 | 49.45 |
| 7.453 | 11.863 | 10.26 |
| 6.054 | 14.618 | 3.35 |
| 5.716 | 15.487 | 14.10 |

| | | |
|---|---|---|
| 5.435 | 16.294 | 33.06 |
| 5.082 | 17.434 | 100.00 |
| 4.844 | 18.296 | 14.06 |
| 4.661 | 19.023 | 5.88 |
| 4.278 | 20.744 | 8.50 |
| 4.116 | 21.570 | 17.02 |
| 3.869 | 22.965 | 36.43 |
| 3.565 | 24.950 | 11.58 |
| 3.337 | 26.690 | 6.65 |
| 3.125 | 28.531 | 11.60 |
| 2.993 | 29.823 | 3.93 |
| 2.778 | 32.194 | 4.65 |
| 2.718 | 32.918 | 4.19 |
| 2.619 | 34.196 | 3.28 |
| 2.551 | 35.140 | 2.52 |
| 2.482 | 36.151 | 1.83 |
| 2.391 | 37.578 | 1.77 |
| 2.245 | 40.129 | 0.69 |
| 2.077 | 43.534 | 0.94 |

comprising,

reaction of a solution of perindopril of formula (I),




(I)

in a solvent selected from N,N-dimethylformamide, ~~or~~ dimethyl acetals of lower aliphatic aldehydes, dimethyl ketals of lower aliphatic ketones and 1, 2-dialkoxyethane ~~and ketones~~ with tertiary butylamine and crystallization of the erbumine salt thus obtained by heating the reaction mixture to reflux, filtering hot to remove any insoluble or suspended matter, cooling to $20^0$C to $30^0$C and further cooling to $0^0$ C to $15^0$ C for 30 minutes to 1 hour and finally filtering off and drying the crystals.

**Replace the Paragraph at Page 28, lines 6-10 with:**

Perindopril prepared by any of the methods mentioned hereinabove was converted to perindopril erbumine (II) and crystallized from N,N-dimethylformamide, ~~or~~ dimethyl acetals of lower aliphatic aldehydes, dimethyl ketals of lower aliphatic ketones and 1, 2- dialkoxyethane ~~and ketones~~ selected from dimethoxymethane, 1,2-dimethoxyethane and 2,2-dimethoxypropane as detailed hereinbelow.

**Replace the Paragraph at Page 40, lines 12-19:**

The above results clearly reveal that perindopril (I) prepared by any method and converted to perindopril erbumine (II) in a solvent selected from N,N-dimethylformamide and dimethyl acetals of lower aliphatic aldehydes, dimethyl ketals of lower aliphatic ketones and 1, 2- dialkoxyethane ~~or ketones~~ and crystallized from the said solvent(s) gives crystalline perindopril erbumine (II), possessing a X-ray (powder) diffraction pattern, IR spectrum and DSC spectrum identical and/or superimposable with the crystalline form of perindopril erbumine obtained by crystallization from ethyl acetate, as per the method described in US. 4 914 214.

**Replace the Paragraph at Page 40, lines 21-26 with:**

In particular, the solvents utilized in the present invention for crystallization of perindopril erbumine i. e. N,N-dimethylformamide, ~~or~~ dimethyl acetals of lower aliphatic aldehydes, dimethyl ketals of lower aliphatic ketones and 1, 2-dialkoxyethane ~~and ketones~~ unlike those used in the prior art, such as acetonitrile, 1,4-dioxane, dichloromethane, chloroform etc. are tolerated better by International Conference on Harmonization (ICH), and thereby rendering the process more amenable for commercial manufacture from a safety, environmental and regulatory point of view.

**Replace the Paragraph at Page 40, line 28 to Page 41, line 4 with:**

Further, perindopril erbumine obtained from crystallization of perindopril erbumine from N,N-dimethylformamide, ~~or~~ dimethyl acetals of lower aliphatic aldehydes, dimethyl ketals of lower aliphatic ketones and 1, 2- dialkoxyethane ~~and ketones~~ was found to possess improved physical characteristics like Particle Size, ~~Fowability~~ Flowability or Compressability Index etc. compared to the material obtained by crystallization from ethyl acetate. These characteristics result in improved dissolution profile, which in turn, results in improved bioavailability, thereby rendering the crystalline perindopril erbumine obtained by the process of the present invention more amenable for formulation into a suitable dosage form. These advantages form the basis of the present invention.